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10/597,307	09/05/2007	Andrea Marziali	B719 0005/GNM	9154

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EXAMINER	
NOGUEROLA, ALEXANDER STEPHAN	
ART UNIT	PAPER NUMBER
1759	

NOTIFICATION DATE	DELIVERY MODE
06/24/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mail@patentable.com

Office Action Summary	Application No.	Applicant(s)	
	10/597,307	MARZIALI ET AL.	
	Examiner	Art Unit	
	ALEX NOGUEROLA	1759	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *4/08/2011 (election)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☒ Claim(s) *See Continuation Sheet* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 June 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *07/29/2010; 11/19/2010; and 12/12/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-17,20-35,38,42-47,50-52,55,56,61-65,68-112,141-153,162,164,165,182,185 and 186.

Continuation of Disposition of Claims: Claims rejected are 1-4,7,8,12-14,27-29,32,34,77,78,80-82,84,85,88,89,92,95,96,141,142,144,145,149,151,182 and 186.
Continuation of Disposition of Claims: Claims objected to are 5,6,9-11,15-17,20-27,30,31,34,35,38,42-47,50-52,55,56,61-65,68-76,79,86,87,90,91,93,94,97-112,143,146-148,150,152,153,162,164,165 and 185.

DETAILED ACTION

Drawings

1. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference characters "125" and "25" have both been used to designate a capillary. See specification paragraph [0150]. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

2. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference signs mentioned in the description: "21A" and "21B" are not present in Figure 4 as stated in specification paragraph [0073].. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Election/Restrictions

3. The Examiner acknowledges Applicant's various species elections. With regard to the traversal gel and micro-fabricated structures as separate species, to the extent they are claimed together the Examiner will consider them both (if properly supported by the original disclosure).

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claims 1, 12-14, 77, 78, 80, 82, 84, 85, 88, 89, 95, 96, 141, 142, 144, 145, 149, 151, 182 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Serwer et al. US 5,185,071 ("Serwer")

Addressing claim 1, Serwer discloses a method for causing motion of particles in a medium (see the abstract and col. 01:01-24), the method comprising:

applying a time-varying driving field to the particles, the driving field applying a time-varying driving force alternating in direction to the particles ("As disk **20** rotates, the angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both) causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-

37.); and, applying a mobility-varying field to the particles, the mobility-varying field being one or both of: different in type from the driving field ("In addition to the rotating means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, "Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35.), and non-aligned with the driving field ("Thus, the control board of the present invention offers independent control of electric field and temperature." See col. 04:46-48. Also, "Both electrical field and temperature regulation are achieved either in conjunction or independent of each other during PFG [Pulsed field gel] electrophoresis." See

col. 04:60-63.);

wherein the driving field and mobility-varying field are applied simultaneously during a period and the mobility-varying field causes a mobility of the particles in the medium to be time dependent during the period, in a manner having a non-zero correlation with the driving field over the period ("The invention utilizes a user-programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (PFG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13.).

Addressing claims 12 and 13, in Serwer the driving field can be a pulsed electric field while the mobility-varying field is temperature.

Addressing claims 14, 77, 78, 80, 82, 84, and 85, in Serwer the particles may be DNA, DNA-protein complexes, proteins, or peptides, for example. See the abstract and col. 06:15-26.

Addressing claims 88, 89, 144, and 145, for the additional limitations of these claims see in Serwer col. 06:07, for example.

Addressing claims 95, 96, and 142, for the additional limitations of these claims see in Serwer Figure 1 and col. 05:66-67.

Addressing claims 141, 149, and 151, Serwer discloses an apparatus for concentrating particles (see the abstract), the apparatus comprising:

a body of a medium (gel) in which the particles are mobile (abstract);

a first field source coupled to deliver a time-varying driving field to the medium

the driving field capable of applying a time-varying driving force alternating in direction to particles in the medium ("As disk **20** rotates, the angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both)

causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also note the electrodes and power supply disclosed in col. 06:64- col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-37.); and,

a second field source coupled to deliver a time-varying mobility-varying field to the medium, the mobility-varying field being one or both of: different in type from the driving field, and non-aligned with the driving field ("In addition to the rotating means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, "Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35. Note Peltier cell 42 in Figure 1.); and,

a control system configured to apply the driving field and mobility-varying field simultaneously to at least a portion of the medium during a period (see Figure 2. Also, "The invention utilizes a user-programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (PFG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13.).

Addressing claim 182, Serwer discloses an apparatus for causing motion of particles in a medium, the apparatus comprising:

a first means for applying a time-varying driving field to the particles, the driving field applying a time-varying driving force alternating in direction to the particles ("As disk **20** rotates, the angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both) causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also note the electrodes and power supply disclosed in col. 06:64- col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-37.); and,

a second means for applying a mobility-varying field to the particles, the mobility-varying field being one or both of: different in type from the driving field, and non-aligned with the driving field ("In addition to the rotating means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, "Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35. Note Peltier cell 42 in Figure 1.);

a means for operating the first and second means in a coordinated manner so that the driving field and mobility-varying field are applied simultaneously during a

period and the mobility-varying field causes a mobility of the particles in the medium to be time dependent during the period, in a manner having a non-zero correlation with the driving field over the period ("The invention utilizes a user-programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (PFG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13. Also, the first and second means may be operated independently, yet simultaneously. See clam 13, col. 04:46-48, and col. 04:60-64.).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 2-4, 7, 8, 32, 34, 81, 92 are rejected under 35 U.S.C. 103(a) as being unpatentable over Serwer.

Addressing claims 2 and 34, Serwer discloses a method for causing motion of particles in a medium (see the abstract and col. 01:01-24), the method comprising:

applying a time-varying driving field to the particles, the driving field applying a time-varying driving force alternating in direction to the particles ("As disk **20** rotates, the

angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both) causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-37.); and, applying a mobility-varying field to the particles, the mobility-varying field being one or both of: different in type from the driving field ("In addition to the rotating means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, 'Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35.), and non-aligned with the driving field ("Thus, the control board of the present invention offers independent control of electric field and temperature." See col. 04:46-48. Also, "Both electrical field and temperature regulation are achieved either in conjunction or independent of each other during PFG [Pulsed field gel] electrophoresis." See col. 04:60-63.);

wherein the driving field and mobility-varying field are applied simultaneously during a period and the mobility-varying field causes a mobility of the particles in the medium to be time dependent during the period, in a manner having a non-zero correlation with the driving field over the period ("The invention utilizes a user-

programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (P{FG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13).

Although Serwer does not explicitly mention having the driving field (electric field) apply a periodically varying driving force to the particles, this is strongly suggested, if not implied, by the disclosure of using a pulsed electric field. See, e.g., col. 01:15-19 and col. 10:33-57.

Addressing claim 3, although Serwer does not explicitly mention having the driving force average to zero over an integral number of cycles of the driving field, Serwer does disclose experimenting with how the driving field is periodically varied to see its effect upon particle migration. See, e.g., col. 10:33-57. Thus, the additional limitation of claim 3 is, barring evidence to the contrary, such as unexpected results, just optimization of a known result effective variable.

Addressing claim 4, although Serwer does not explicitly mention having the mobility-varying field cause the mobility of the particles to vary periodically, since Serwer does disclose independently and programmably controlling the mobility-varying field (col. 04:46-50 and col. 03:58-63), the additional limitation of this claim seems to be just optimization of a known result effective variable.

Addressing claims 7 and 32, the mobility-varying field in Serwer is a thermal field, particularly a chilling field. If no electric field is applied to the particles, but a cooling field was applied to 10ºC, for example (col. 08:46-49), one with ordinary skill at the time of the invention would expect no net motion of the particles (biomolecules, such as DNA).

Addressing claim 8, one with ordinary skill in the art at the time of the invention would recognize that the electric field and temperature have a synergistic effect on particle mobility.

Addressing claim 81, Serwer discloses a method for causing motion of particles in a medium (see the abstract and col. 01:01-24), the method comprising:

applying a time-varying driving field to the particles, the driving field applying a time-varying driving force alternating in direction to the particles ("As disk **20** rotates, the angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both) causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-37.); and, applying a mobility-varying field to the particles, the mobility-varying field being one or both of: different in type from the driving field ("In addition to the rotating

means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, 'Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35.), and non-aligned with the driving field ("Thus, the control board of the present invention offers independent control of electric field and temperature." See col. 04:46-48. Also, "Both electrical field and temperature regulation are achieved either in conjunction or independent of each other during PFG [Pulsed field gel] electrophoresis." See col. 04:60-63.);

wherein the driving field and mobility-varying field are applied simultaneously during a period and the mobility-varying field causes a mobility of the particles in the medium to be time dependent during the period, in a manner having a non-zero correlation with the driving field over the period ("The invention utilizes a user-programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (P{FG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13).

Although Serwer does not appear to mention RNA, since Serwer does mention the very similar DNA as particles, RNA will be considered an obvious variant of particle type.

Addressing claim 92, Serwer discloses a method for causing motion of particles in a medium (see the abstract and col. 01:01-24), the method comprising:

applying a time-varying driving field to the particles, the driving field applying a time-varying driving force alternating in direction to the particles ("As disk **20** rotates, the angle of incidence of electric field upon the sample particles changes. It is found that electrophoresis performed by an electric field which varies in either magnitude and direction (or both) causes improved fractionation of large DNA molecules (...)" See col. 06:67 – col. 07:05. Also, "An electric field is then applied to the rotating bed causing varying angles of incidence in response to programmed input." See col. 04:34-37.); and, applying a mobility-varying field to the particles, the mobility-varying field being one or both of: different in type from the driving field ("In addition to the rotating means and field controlling means, the present invention also includes a programmable temperature control means, such as Peltier means, connected to the holding tanks. The Peltier means regulates the temperature of the buffer solution contained within the tanks and across the gel bed." See col. 03:58-63. Also, 'Cooling of buffer solution is important for achieving accurate control of DNA migration." See col. 07:34-35.), and non-aligned with the driving field ("Thus, the control board of the present invention offers independent control of electric field and temperature." See col. 04:46-48. Also, "Both electrical field and temperature regulation are achieved either in conjunction or independent of each other during PFG [Pulsed field gel] electrophoresis." See

col. 04:60-63.);

wherein the driving field and mobility-varying field are applied simultaneously during a period and the mobility-varying field causes a mobility of the particles in the medium to be time dependent during the period, in a manner having a non-zero correlation with the driving field over the period ("The invention utilizes a user-programmable control board for multiplexing the control of both electric field (magnitude and direction) and temperature during either pulsed field gel (P{FG) or invariant field gel electrophoresis". See col. 01:15-19 and claim 13).

Although Serwer does not appear to mention acrylamide or polyacrylamide gel since acrylamide or polyacrylamide gel is perhaps the best known and most commonly used type of electrophoresis gel the selection of such a gel is just substitution of one known gel type (acrylamide or polyacrylamide) for another (for example, agarose) with predictable results.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 27-29 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 27 appears to be inconsistent with claim 1 from which it depends. Claim 1 requires "... applying a time-varying driving force *alternating in direction* to the particles; ...[emphasis added]", yet claim 27 requires "an alternating electric field *aligned in a first direction*. [emphasis added]"

12. Claim 186 recites the limitation "time-varying flow" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

13. Note that dependent claims will have the deficiencies of base and intervening claims.

Allowable Subject Matter

14. Claims 5, 6, 9-11, 15-17, 20-27, 30, 31, 34, 35, 38, 42-47, 50-52, 55, 56, 61-65, 68-76, 79, 86, 87, 90, 91, 93, 94, 97-112, 143, 146-148, 150, 152, 153, 162, 164, 165, 185 are objected to as being dependent upon a rejected base claim, but would be

allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

15. Claims 27-29 and 186 would be allowable if rewritten to overcome the rejections under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

16. The Search Report for International application No. PCT/CA2005/000124 lists only "A" references.

17. The Written Opinion for International application No. PCT/CA2005/000124 deemed the examined claims novel and inventive.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY BARTON can be reached at (571) 272-1307. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Alex Noguerola/
Primary Examiner, Art Unit 1759
June 20, 2011